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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/628,315

07/28/2003

Janice Hansen

6978/79209

4453

22242 7590 09/10/2008  
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EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

09/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/628,315	<b>Applicant(s)</b> HANSEN, JANICE	
	<b>Examiner</b> SUZETTE J. GHERBI	<b>Art Unit</b> 3738	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/18/04</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Objections*

Claims 9 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In particular claim 9 recites the same limitations as stated in claim 7.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1-26 claims “sebaceous ***glands*** (***Montgomery follicles***) and sweat ***glands***”, and is therefore positively claiming a living tissue. The living matter of the present invention is not the result of human intervention; it is of nature, which has been held not patentable.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-8, 10-14, and 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis 5,171,321 in view of Knoche 4,356,573 and further in view of Woodley 5,782,672.

Davis discloses a nipple prosthesis comprising a thin, flexible areola ((14) 2:23-25), a rounded nipple portion (16), adjustable height and size 2:16-22, thermoplastics, rubber, vinyl-PVC, polypropylene, colored and flavored material 2:25-32; a circular adhesive surface (19) and a diameter of the areola being between 0.5 and 3 inches 3:39-42; however Davis does not specify rounded shapes that represent sebaceous and sweat glands.; an adhesive on the outer concave surface of the areola, a square nipple shap, a nipple having a height between 0.25 and 1 inch, or a circular cut line extending around the areola. It would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the shape of the nipple to be square to more replicate alternate shapes over various peoples anatomies and is deemed a design modification.

Knoche teaches a breast prosthesis that has rounded glands that represent sebaceous and sweat glands as shown in figures 1-3. It would have been obvious to

Art Unit: 3738

one having ordinary skill in the art to take the nipple prosthesis of Davis and incorporate these rounded shapes of Knoche to provide a more natural looking appearance.

Woodley teaches a nipple cover having at least one circular cut line (see figures 203 and 3:40) extending around the areola. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate circular cut lines extending around the areola to allow the patient /user to adjust the size of the areola and nipple prosthesis.

Regarding the adhesive it would have been obvious to one having skill in the art to utilize adhesive on the outer concave surface of the areola device since it has been held that mere duplication of the essential working parts involves only routine skill in the art. *St Regis Paper Co v. Bernis Co.*, 193 USPQ 8.

Absent teachings as to the criticality of a nipple having a height of between 0.25 and 1 inches, this particular arrangement is deemed to have been known by those skilled in the art since the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement. *In re Kuhle*, 526 F.2d 555, 188 USPQ 7, 9 (CCPA 1975).

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J-J Gherbi whose work schedule is Maxi-Flex off every other Friday and whose telephone number is 571-272-4751.

Art Unit: 3738

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suzette J Gherbi/  
Primary Examiner, Art Unit 3738  
09 September 2008